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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,111	02/18/2004	Rogier Receveur	P10926.00	1950
27581	7590	09/14/2006	EXAMINER BERTRAM, ERIC D	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			ART UNIT 3766	
DATE MAILED: 09/14/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/781,111	Applicant(s) RECEVEUR ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-20 is/are allowed.
- 6) ☒ Claim(s) 1 and 3-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/11/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6/29/2006 regarding the 35 USC 102(e) rejection of claims 1, 2, 5, 6, 8-12, 14 and 15 as being anticipated by Hunter et al. (US 2004/0097806, hereinafter Hunter) have been fully considered but they are not persuasive. The Applicant argues that Hunter is devoid of any teaching regarding navigation of a medical electrical lead through a portion of a coronary sinus based on differing temperature of blood.
2. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., navigation based on differing of temperature) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Specifically, claim 1 only recites "sensing a physical parameter relating to a distinguishing characteristic of blood present within a right atrium and blood exiting from a coronary sinus into the right atrium." Furthermore, claim 12 merely recites "means for sensing a physical parameter...relating to a blood temperature said [sic] right atrial chamber and a temperature of blood exiting a coronary sinus." It should be noted that no comparison is being made between blood in the right atrium and blood leaving the coronary sinus, and therefore, the distinguishing characteristic does not necessarily need to refer to a differing temperature of blood. As written, as long as a temperature sensor is present that can sense the temperature (a

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distinguishing characteristic) of both the blood in the right atrium and blood leaving the coronary sinus, the limitations of the claims are met.

3. Hunter describes a navigational system that allows for the placement of a medical lead in the coronary sinus of a patient (par. 0062, 0063 and 0073). Hunter then discloses employing a temperature sensor and monitoring the data from the sensor in order to navigate the lead within the body (par. 0067). Therefore, all of the limitations in claims 1 and 12 are met by Hunter, as described above and in the rejection found below. As a result, the 35 USC 102(e) rejection of claims 1, 2, 5, 6, 8-12, 14 and 15 as being anticipated by Hunter is still considered valid.

4. Applicant's arguments regarding the 35 USC 103(a) rejection of claims 3 and 4 as being unpatentable over Hunter in view of Lesh et al. (US 5,385,148, hereinafter Lesh) have been fully considered but they are not persuasive. The Applicant argues that since Lesh deals with ablation of myocardial tissue and not navigation of cardiac leads, it would be improper to combine Lesh with Hunter. However, the inclusion of Lesh is merely to show that the use of a thermistor or a thermocouple as a temperature sensor in an implanted medical electrical lead is old and well known in the art. Hunter discloses all of the limitations regarding navigation of an implanted medical electrical lead including a temperature sensor. Lesh teaches the use of a thermistor or a thermocouple as a temperature sensor in an implanted medical electrical lead. Therefore, it would have been obvious to one of ordinary skill to use a thermistor or a thermocouple in any implantable medical lead, including the lead of Hunter. As a result,

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the 35 USC 103(a) rejection of claims 3 and 4 as being unpatentable over Hunter in view of Lesh is still considered valid.

5. Applicant's arguments regarding the 35 USC 103(a) rejection of claims 7 and 13 as being unpatentable over Hunter in view of Zanelli et al. (US 6,024,703, hereinafter Zanelli) have been fully considered but they are not persuasive. Applicant argues that Zanelli does not deal with the claimed subject matter in any meaningful manner.

However, Zanelli includes a general teaching for all medical devices that visual and audio alarms and signals greatly increase the safety of a medical device (Col. 10, lines 46-54). Hunter includes a teaching of using visual signals to communicate navigational commands with a physician, but is silent as to the use of audio commands. Since Zanelli includes a general teaching of the added safety to a medical device by using audio, it would have been obvious to one of ordinary skill in the art to include audio commands in addition to video commands in order to ensure the safety of the patient. As a result, the 35 USC 103(a) rejection of claims 7 and 13 as being unpatentable over Hunter in view of Zanelli is still considered valid.

6. Applicant's arguments with respect to claims 16-20 have been fully considered and are persuasive. The 35 USC 103(a) rejections of claims 16-20 have been withdrawn.

Specification

7. The amendments to the specification are acknowledged and accepted. The objection to the specification has been withdrawn.

Information Disclosure Statement

8. The information disclosure statement filed 9/11/2006 fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 2, 5, 6, 8-12, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunter. Hunter discloses a catheter 52 that is navigable within a cardiac anatomy for delivering a medical electrical lead (par. 0043 and 0063). Disposed on the catheter is a plurality of sensors 58, including pressure, optical, oxygen, temperature and electromagnetic sensors for sensing physical parameters (para. 0043 and 0067 and 0076). As shown in figure 1, the sensors are communicatively coupled with workstation 34, which inherently includes a processor. The workstation receives the physical parameters and manipulates them into navigational data (para. 0016 and 0049). The workstation is then communicatively coupled to a display 36, which displays navigational data relating to the sensors and the catheter (para. 0049). Hunter further

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discloses an imaging device 12 which provides patient image data that is displayed in association with sensed parameters, including from magnetic field sensors as well as physical parameters from the body such as temperature and pressure (para. 0049). By combining this information, one can receive visual direction and confirmation to an anatomical location.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter in view of Lesh. Hunter, as described above, discloses the applicant's basic invention with the exception of disclosing that the temperature sensors can be a thermistor or a thermocouple. Attention is directed to the secondary reference of Lesh, who discloses an implantable lead utilizing a temperature sensor comprising a thermistor or a thermocouple (Col. 5, lines 40-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use a thermistor or a thermocouple as a temperature sensor on an implantable lead since their use is old and well known in the art.

13. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter in view of Zanelli. Hunter, as described above, discloses the applicant's basic invention including outputting information to a physician. However, Hunter does not

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disclose that the output is audible in nature. Attention is directed to the secondary reference of Zanelli, which discloses that the use of visual and audio outputs increase the safety of an implantable system (Col. 10, lines 46-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Hunter by adding audio outputs in order to increase the safety of the system since the physician would not have to look at a screen to receive instructions, but could hear them while focusing on the procedure.

Allowable Subject Matter

14. Claims 16-20 are allowable over the prior art of record.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

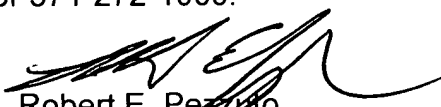
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

EDB